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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,521	12/05/2003	Atul Varadhachary	HO-P02703US2	8270

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,521	VARADHACHARY ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-10,14-20,26-32,38-40,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-10,14-19,26-32,38-40,45 and 46* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O.

DETAILED ACTION

Status of the Claims

1. Claims 1, 7-10, 14-20, 26-32, 38-40, 45 and 46 are pending.

Applicants' amendment filed April 11, 2005 is acknowledged. Applicant's response has been fully considered. Claims 1, 26, 27, 31, 32 and 38 have been amended, claims 2-6, 11-13, 21-25, 33-37 and 41-44 have been cancelled, and new claims 45 and 46 have been added. Therefore, claims 1, 7-10, 14-20, 26-32, 38-40, 45 and 46 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1, 7-20, 27 and 32 under 35 U. S. C. 112, second paragraph as being indefinite, is withdrawn in view of applicant's cancellation of the claim, applicant's amendment to the claim, and applicant's response at page 6 in the amendment filed April 11, 2005.

Claim Rejections - 35 USC § 102

3. The previous rejection of claims 1-9, 15, 17, 20, 26-32 and 34-40 under 35 U. S. C. 102(b) as being anticipated by Kruzel *et al.* (International Congress Series (2000), 1195 (Lactoferrin, Structure, Function and Applications), 301-310), is withdrawn in view of applicant's cancellation of the claim, applicant's amendment to the claim, and applicant's response at page 7 in the amendment filed April 11, 2005.

4. The previous rejection of claims 1-10, 15, 17, 20, 26, 27 and 31-38 under 35 U. S. C. 102(b) as being anticipated by Edde *et al.* (Am. J. Physiol. Gastrointest. Liver Physiol. 281, G1140-G1150, November 2001), is withdrawn in view of applicant's cancellation of the claim,

applicant's amendment to the claim, and applicant's response at page 7 in the amendment filed April 11, 2005.

5. The previous rejection of claims 1-10, 15-20, 26-32 and 34-40 under 35 U. S. C. 102(b) as being anticipated by Kruzel *et al.* (US 2001/0056067, filed October 29, 1999), is withdrawn in view of applicant's cancellation of the claim, applicant's amendment to the claim, and applicant's response at page 8 in the amendment filed April 11, 2005.

Claim Rejections - 35 USC § 103

6. The previous rejection of claims 2, 11 and 12 under 35 U. S. C. 103(a) as being unpatentable over by Van Bree *et al.* (WO 01/72322, October 4, 2001), is withdrawn in view of applicant's cancellation of the claim in the amendment filed April 11, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 8-10, 15, 16, 28, 30 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 8 recites the limitation "said lactoferrin" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 1 recites N-terminal lactoferrin variant, not lactoferrin. See also claims 9-10, 15, 16, 28 and 30.

9. Claim 46 is indefinite because the claim recites the term "said N-terminal lactoferrin variant comprises at least 1% to at least 50% of the lactoferrin composition", while claim 26, 27, 31, 32 or 38, from which claim 46 depends from, cites "said lactoferrin composition consisting

essentially of an N-terminal lactoferrin variant", it is not clear how the N-terminal lactoferrin variant, which is a peptide, can consisting essentially of at least a portion (1-50%) of the lactoferrin composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 7-10, 14-19, 26-32, 38-40, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Van Bree *et al.* (WO 01/72322, October 4, 2001).

Van Bree *et al.* teach human lactoferrin (hLF) can block free LPS and cause them to clear from the body more rapidly, and mask their inflammatory activity; and hLF or LF variants (e.g., N-terminal variants, hLF(1-11), hLF(2-11) and hLF(3-11); page 27; claim 45), which have the biological activities of natural LF, can be used to treat large scale (bacterial) infection, blood-borne infection (sepsis) as well as inflammation resulting from an infection (pages 3-4; page 20,

lines 24-29; page 24; claims 1, 8, 9), where the concentration of the polypeptide (LF or LF variant) in the pharmaceutical composition can be at least 1% to 20% by weight, or the peptide/fragment can be administered about 0.19 mg/kg to 19 mg/kg daily (corresponding to 10-100 mg/kg of intact lactoferrin; about 11.4 mg to 114 mg daily assuming weight of a person is about 60 kg; page 24; claims 15, 16 and 46). The lactoferrin variants can be produced by proteolytic cleavage of LF or recombinant technique (pages 11-13; claim 10); and lactoferrin/variant can be administered orally in the form of a solid or solution, and the active components can be encapsulated in gelatin capsules together with inactive ingredients and carriers such as glucose, mannitol or magnesium carbonate (an antacid; claim 14), and the formulated solid or liquid formulations can be in an enteric-coated form (page 26; claims 7, 17-19). Although the reference does not provide a specific example for a method of treating bacteremia, enhancing a mucosal immune response or decreasing mortality using a lactoferrin composition containing the N-terminal variant, it indicates a high dose of hLF or LF variant (e.g., N-terminal variant) having the biological activity of natural LF can be orally administered in the treatment, which has the same method step as the claimed invention, thus at the time of invention was made, it would have been obvious to one of ordinary skill in the art to orally administer N-terminal variant of LF in the method of treating bacteremia, enhancing a mucosal immune response or decreasing mortality to produce the desired effect as the LF (claims 26-32, 38-40) which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

In response, applicants indicate Van Bree *et al.* do not teach or suggest the use of a lactoferrin composition consisting essentially of at least 1%-50% of N-terminal lactoferrin

variant in the treatment (pages 8-9 of the response). Applicants' response has been considered, however, the argument is not found persuasive because Van Bree *et al.* do indicate the concentration of the polypeptide (LF or LF variant) in the pharmaceutical composition can be at least 1% to 20% by weight (page 24, lines 10-12; page 25, lines 22-24), which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Claim Objections

10. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. Claims 1, 7-10, 14-19, 26-32, 38-40, 45 and 46 are rejected, and claim 20 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
June 15, 2005